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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Ijeoma UCHEGBU et al.

Application No. 10/528,602

Filing Date: September 29, 2005

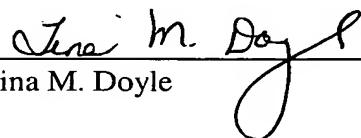
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: Examiner: Not Yet Assigned  
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: Group Art Unit: Not Yet Assigned  
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Our File No. 0380-P03603US00

**Certificate of Mailing Under 37 C.F.R. §1.8(a):**

I hereby certify that this correspondence is being deposited on August 18, 2006 with the United States Postal Service as first-class mail in an envelope properly addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

  
Tina M. Doyle

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97**

In compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, Applicants are submitting herewith a Form PTO-1449 and a copy of the references listed thereon. This Supplemental Information Disclosure Statement is being filed more than three months after the filing date of the application. However, Applicants have not yet received an action on the merits of the application. Accordingly, Applicants believe that no fee is required pursuant to 37 C.F.R. §1.97 (b) (3). In the event a fee is required, the Commissioner is authorized to charge the required fees to Deposit Account No. 04-1406. A duplicate copy of this sheet is

U.S. Patent Application No.  
10/528,603

included for fee processing, if necessary.

This submission is not an admission that the references listed on the attached Form PTO-1449 constitute prior art against the claims of this application.

The Examiner is respectfully requested to confirm receipt and consideration of the cited references by initialing and returning a copy of the attached Form PTO-1449 in accordance with MPEP §609.

Applicants respectfully request full and proper consideration of the listed information during examination of the application, and that the listed information be printed on any patent that issues therefrom.

Respectfully submitted,

DANN, DORFMAN, HERRELL & SKILLMAN  
A Professional Corporation  
Attorneys for Applicant(s)

By Patrick J. Hagan  
Patrick J. Hagan  
PTO Registration No. 27,643

Enclosures - Form PTO-1449  
Copies of references listed on PTO - 1449

# INFORMATION DISCLOSURE STATEMENT



SHEET 1 OF 2

Complete if known

Application Number: 10/528,602

Filing Date: September 29, 2005

First Named Inventor: Ijedma UCHEGBU

Group Art Unit: Not Yet Assigned

Examiner Name: Not Yet Assigned

Our File No. 0380-P03603US00

## UNITED STATES PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	PATENT NUMBER	ISSUE DATE MM-DD-YYYY	FIRST NAMED INVENTOR
	A1			
	A2			
	A3			
	A4			

## FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	DOCUMENT NUMBER	COUNTRY OR REGION	DATE OF PUBLICATION MM-DD-YYYY	FIRST NAMED INVENTOR OR APPLICANT
	B1				
	B2				
	B3				
	B4				

## OTHER PRIOR ART - NON-PATENT DOCUMENTS

EXAMINER'S INITIALS	CITE NO.	Include name of the author (in Capital Letters), title of the article (when appropriate), title of the item(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	C1	DUNN, C.J., WAGSTAFF, A.J., PERRY, C.M., PLOSKER G.L., GOA, K.L., <i>Cyclosporin - An Updated Review of the Pharmacokinetic Properties, Clinical Efficacy and Tolerability of a Microemulsion-Based Formulation Neoral R(1) in Organ Transplantation</i> , Drugs, <u>61</u> : 1957-2016 (2001)
	C2	PORTER, C.J.H., CHARMAN, W.N., <i>In Vitro Assessment of Oral Lipid Based Formulations</i> , Advanced Drug Delivery Reviews, <u>50</u> : S127-S147 (2001)
	C3	BALANDRAUD-PERI, N., QUENEAU, P.E., CAROLI-BOSC, F.X., BERTAULT-PERES, P., MONTET, A.M., DURAND, A., MONTET, J.C., <i>Effects of Tauroursodeoxycholate Solutions on Cyclosporin and Bioavailability in Rats</i> , Drug Metabolism and disposition, <u>25</u> : 912-916 (1997)

EXAMINER'S  
SIGNATURE

DATE  
CONSIDERED

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw a line through citation if citation not in conformance and reference not considered. Include a copy of this form with next communication to applicant.

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Group Art Unit: Not Yet Assigned

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SHEET 2 OF 2

Our File No. 0380-P03603US00

C4	GUO, J.X., PING, Q.N., CHEN, Y., <i>Pharmacokinetic Behaviour of Cyclosporin A in Rabbits by Oral Administration of Lecithin Vesicle and Sandimmun Neoral</i> , International Journal of Pharmaceutics, <u>216</u> : 17-21 (2001)
C5	PORTER, C.J.H., CHARMAN, S.A., WILLIAMS, R.D., BAKALOVA, M.B., CHARMAN, W.N., <i>Evaluation of Emulsifiable Glasses for the Oral Administration of the Cyclosporin in Beagle Dogs</i> , International Journal of Pharmaceutics, <u>141</u> : 227-237 (1996)
C6	LEIGH, M., HOOGEVEST, P.V., TIEMIESSEM, H., <i>Optimising the Oral Bioavailability of the Poorly Water Soluble Drug Cyclosporin A Using Membrane Lipid Technology</i> , Drug Delivery and Sciences, <u>1</u> : 73-77 (2001)
C7	MIYAKE, K., ARIMA, H., IRIE, T., HIRAYMA, F., UEKAMA, K., <i>Enhanced Absorption of Cyclosporin A by Complexation with Dimethyl-Beta-cyclodextrin in Bile duct-cannulated and Non-Cannulated Rats</i> , Biological and Pharmaceutical Bulletin, <u>22</u> : 66-72 (1999)
C8	BONDUELLE, S., CARRIER, M., PIMIENTA, C., BENOIT, J.P., LENAERTS, B., <i>Tissue Concentration of Nanoencapsulated Radiolabelled Cyclosporin Following Peroral Delivery in Mice or Ophthalmic Application in Rabbits</i> , European Journal of Pharmaceutics and Biopharmaceutics, <u>42</u> : 31-319

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